For the examiner's convenience, a clean text version of the replacement abstract (93 words) is presented below:

A method for the return of blood from a blood treatment apparatus, preferably from a dialysis apparatus, uses a pumped substituate fluid to displace the blood. A substituate pump contained in the treatment apparatus displaces the blood by means of the correspondingly transported substituate fluid until it is detected in corresponding detectors that substituate fluid is flowing back in the line instead of blood. Once the transported substituate fluid has been detected, the blood volume is further displaced in a controlled manner until it has reached the line outlet of the corresponding line.

Amendments to the Drawings

In accordance with 37 CFR § 1.121(d)(1), attached hereto is one annotated sheet depicting changes made to the sole drawing figure. The attached figure has been amended to delete the "Fig." legend in accordance with 37 CFR § 1.84(u)(1). The reference numbers have been amended to comply with 37 CFR § 1.84(p)(1).

Also attached hereto is one replacement sheet of drawings, incorporating the changes made to the sole figure, which replaces the drawing figure originally submitted with the application.

Remarks

Reconsideration and allowance of this application, as amended, are respectfully requested.

The written description portion of the specification, claims 1-11, the abstract of the disclosure, and the drawing figure have been amended. New claims 12-20 have been added. Claims 1-20 are now pending in the application. Claims 1, 2, and 17 are independent. The rejections are respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments.

The specification has been editorially amended for conformance with 37 CFR § 1.77(c), for consistency, and to correct any informalities. The abstract has been editorially amended for conformance with 37 CFR § 1.72(b). The drawing figure has been amended as described above in the "Amendments to the Drawings" section. Claims 1-11 have been amended to more fully comply with U.S. practice. New claims 12-20 have been added to further define the scope of protection sought for Applicants' invention.

Entry of each of the amendments is respectfully requested.

35 U.S.C. § 103(a) - Twardowski and Polaschegg

Claims 1, 4, 8, and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,132,616 to Twardowski et

al. (hereinafter "Twardowski") in view of DE 42 40 681 to Polaschegg. The Office Action acknowledges that "Twardowski fails to disclose the presence and use of a substituate pump to move the substituate fluid through the circuit" and relies upon Polaschegg for the disclosure of "a dialysis apparatus with a substitute fluid 46 connected via line 44 and pump 50 to blood path 36" (Office Action page 3).

The rejection of claims 1, 4, 8, and 9 under § 103(a) based on Twardowski and Polaschegg is respectfully deemed to be obviated. The combined disclosures of Twardowski and Polaschegg would not have rendered obvious Applicants' presently claimed invention.

By way of review, Applicants' invention is directed to "a method for the return of blood from a blood treatment apparatus, preferably a dialysis apparatus, and to an apparatus to carry out the method" (specification page 1, paragraph 1). The invention addresses the need that "at the end of a dialysis session that the blood present in the extracorporeal circuit [be] returned to the patient as completely as possible" (page 2, paragraph 1). An object of the invention is to provide a method "for a return of blood which is as quantitative as possible . . . [and] which is designed to be even further simplified and more expedient where possible" (page 2, paragraph 2).

Accordingly, Applicants' instant claim 1 defines a predilution method that includes, *inter alia*, the steps of "operating the substituate pump to displace the blood with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the first line outlet" and "operating the substituate pump to displace the blood through the second line and the blood treatment element with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the second line outlet."

The combined disclosures of Twardowski and Polaschegg do not teach all of Applicants' instant claim features. First, as acknowledged by the examiner, "Twardowski fails to disclose the presence and use of a substituate pump to move the substituate fluid through the circuit." Twardowski discloses a hemodialyzer. Twardowski's saline bag 164 serves for the filling of the blood tubing system at the start of treatment and for the return of blood at the end of treatment. Applicants note that it is known in hemodialysis to connect a saline solution bag to the arterial line for this purpose and to fill and to purge the blood tubing system by operating the blood tubing pump at the start of treatment. It is also known to remove the arterial needle from the patient at the end of treatment and to again connect the arterial line to a saline solution bag and to return the blood in the blood tubing system to the patient via the remaining venous connection by operating the

pump. According to Twardowski, the bag 164 is connected to the arterial line via a T connector (saline valve 168). The T connector is located upstream of the blood pump 148. For the return of blood at the end of treatment, the "short" path to the patient is first cleared of blood by gravity, then the patient closes a clamp 145a to interrupt this tube section (the other section is closed by the stationary blood pump) (column 14, lines 39-60). The blood pump is then put into operation and the other part of the blood tubing system is purged.

That is not Applicants' claimed method. As indicated above, according to Applicants' predilution embodiment of the invention the method includes the steps of "operating the substituate pump to displace the blood with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the first line outlet" and "operating the substituate pump to displace the blood through the second line and the blood treatment element with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the second line outlet."

Applicants also note the following differences between Twardowski's method and the instantly claimed method. Twardowski's method is not suitable for hemofiltration treatment or hemodiafiltration treatment since the bag should not be connected via the valve 168 during treatment. A corresponding

ultrafiltration apparatus would also have to be present to compensate for the substituate flow. Additionally, the patient must manually intervene at times. And, the sequence of the purging steps is different. According to Twardowski, the blood pump is not in motion during the return infusion through the arterial connection and it is in forward operation during the return infusion through the venous connection. But, according to Applicants' claimed invention, the blood pump is in pressure control operation (or, allows throughflow) in the arterial case, while it is stationary in the venous case.

Second, the disclosure of Polaschegg does not rectify the above-described deficiencies of Twardowski. While Polaschegg may disclose an occludable actuator (48, 50), Polaschegg fails to teach Applicants' claimed predilution method for the return of blood from a blood treatment apparatus. In addition, according to Polaschegg, the purge line 44 with the pump 50 serves only to purge the system, but not to provide substitution liquid for hemofiltration or hemodiafiltration treatment. This is particularly evident from Polaschegg's Figure 2 which explicitly shows a hemodiafiltration apparatus. Lines 98 and 102 are provided for the post-dilution and the pre-dilution - *in addition to* the purge line 50. It is also notable that the pre-dilution line opens into the blood supply line *downstream* of the blood pump, since otherwise the speed of the blood pump would have to be adapted for the substituate flow.

Thus, the combined disclosures of Twardowski and Polaschegg do not teach all of Applicants' instant claim features. Furthermore, there is simply no teaching in either Twardowski or Polaschegg that would have led one to select the references and combine them in a way that would produce the invention defined by Applicants' presently pending claim 1.

Therefore, the combined disclosures of Twardowski and Polaschegg would not have rendered obvious the invention defined by Applicants' presently pending claim 1. Claims 4, 8, and 9 are allowable because they depend from claim 1, and for other reasons.

35 U.S.C. § 103(a) - Twardowski and Bene

Claims 2 and 5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Twardowski in view of US 5,470,483 to Bene et al. ("Bene"). The Office Action relies upon Bene for the disclosure of "a dialysis apparatus with a substitute fluid 10 connected via line and pump 10 [*sic*, 11] to blood path 7" (Office Action page 4).

The rejection of claims 2 and 5 under § 103(a) based on Twardowski and Bene is respectfully deemed to be obviated. The combined disclosures of Twardowski and Bene would not have rendered obvious Applicants' presently claimed invention.

Applicants' instant claim 2 defines a postdilution method that includes, *inter alia*, the steps of "operating the substituate

pump to displace the blood through the blood treatment element and the first line with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the first line outlet" and "operating the substituate pump to displace the blood through the second line with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the second line outlet."

The disclosure of Bene does not rectify any of the above-described deficiencies of Twardowski. Bene may disclose the use of a substitute fluid and pump for controlling the *balance* of fluids, but fails to teach Applicants' claimed use of a substituate fluid, let alone the postdilution method for the return of blood from a blood treatment apparatus.

Therefore, the combined disclosures of Twardowski and Bene would not have rendered obvious the invention defined by Applicants' presently pending claim 2.

Since Twardowski and Polaschegg are applied together in each of the other rejections under § 103(a) -- claim 3 as being unpatentable over Twardowski in view of Polaschegg and further in view of US 4,770,769 to Schael, and claims 6, 7, 10, and 11 as being unpatentable over Twardowski in view of Polaschegg and further in view of US 5,783,072 to Kenley et al. ("Kenley") -- each of these rejections is also respectfully deemed to be obviated. The combined disclosures of the cited references would not have

rendered obvious Applicants' presently claimed invention because the disclosures of the additional references do not rectify any of the above-described deficiencies of Twardowski and Polaschegg.

New claims 12-20 have been added to further define the scope of protection sought for Applicants' invention. New claims 12-20 are also allowable. Claims 14 and 15, for example, depend from claims 1 and 2, respectively, and recite that "the first line and the second line are used both as conduits for transport of blood during operation of the blood treatment element and as conduits for the return of the displaced blood from the blood treatment apparatus." That is, the same substituate lines are used for an HF treatment or an HDF treatment, on the one hand, and for the blood return process, on the other hand.

New independent claim 17 defines a method of removing blood from a blood treatment apparatus that includes both a predilution mode of operation and a postdilution mode of operation. Since claim 17 includes at least the features discussed above with respect to the rejections over Twardowski and Polaschegg, and Twardowski and Bene, the combinations of references neither anticipate nor would have rendered obvious the method defined by new claim 17. Claims 18-20 are allowable because they depend from claim 17, and for other reasons.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that an

interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: Harvey B. Jacobson, Jr.
Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, N. W.
Washington, D.C. 20004
Telephone: (202) 638-6666
Date: November 13, 2007

Annotated Sheet Showing Changes

Fig.